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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/227,881	01/11/1999	THAI D. NGUYEN	07425.0057	7578

7590

02/25/2003

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EXAMINER

SCHMIDT, MARY M

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 02/25/2003

81

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/227,881

Applicant(s)

NGUYEN ET AL.

Examiner

Mary M. Schmidt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 79-81 and 91-126 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 79-81, 91, 96, 100, 102, 103, 106, 108, 109, 112, 114, 121, 124 and 126 is/are rejected.
- 7) ☒ Claim(s) 94, 115, 118 and 120 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 30.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 92,93,95,98,99,101,104,105,107,110,111,113,116,117,119,122,123 and 125.

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DETAILED ACTION

1. Claims 92, 93, 95, 98, 99, 101, 104, 105, 107, 110, 111, 113, 116, 117, 119, 122, 123 and 125 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 23, filed 10/29/01.
2. Claims 94, 115, 118 and 120 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
3. Applicant is advised that should claim 115 be found allowable, claim 118 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 79, 80, 81, 91, 96, 97, 100, 102, 103, 106, 108, 109, 112, 114, 115, 121, 124 and 126 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to fragments of SEQ ID NO:3 that possess a functional regulatory region and are at least about 8 nucleotides in length. The specification as filed teaches on pages 13-24 several art recognized consensus motifs that are known regulatory regions in genes of gene promoters. The claims, however, remain broadly drawn, with open “comprising” language, to any size fragment of SEQ ID NO:3 that possesses a function regulatory region and is at least about 8 bases in length. The fragments claimed thus embrace a broad scope of sequences that are not taught by way of sequence structure in the specification as filed. They read on fragments at least 8 bases of SEQ ID NO:3 that are considered a regulatory region, but further embrace any other unspecified sequence which one of skill in the art would not be able to readily envisage from the teachings of the specification as filed. As pointed out in the previous Office action, MPEP 2163 states that a biomolecule sequence described only by a functional characteristic (in this case, having a functional regulatory region), without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. Absent further teaching of a representative number of species befitting the breadth of the claimed genus, one of skill in the art would not have recognized that applicant was

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in possession of a representative number of species of the claimed fragments at the time the invention was made.

Response to Arguments

6. Applicant's arguments filed 12/09/02 have been fully considered but they are not persuasive.

Applicants state on page 6 of the response that "Applicants maintain that they need not identify and correlate functional regions of the claimed nucleic acids to meet the written description requirement where they have provided "a precise definition, such as by structure [and] formula."

However, as argued above, applicants have not provided a representative number of species of any 8-mer fragment of SEQ ID NO:3 that has any possible functional regulatory region such that the nexus between the claimed sequences and the claimed functions has been clearly established so that one of skill in the art could readily envisage a representative number of species of any such fragment. In view of the open comprising language, the claimed fragments are not just drawn to fragments of SEQ ID NO:3, but embrace additional sequences added on to any such fragment of SEQ IDNO:3. As such, the claims read broadly on any gene having an 8-mer of SEQ IDNO:3, the breath of which is not adequately described by the specification as filed.

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Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 79, 100 and 102 are rejected under 35 U.S.C. 102(e) as being anticipated by Chojkier et al. (U.S. Patent 6,075,027).

Claim 79 is drawn to a substantially purified nucleic acid comprising a nucleotide sequence of SEQ ID NO:3 that possesses a functional regulatory region and is at least about 8 nucleotides in length. Claim 100 states the nucleic acid of claim 97, wherein the nucleotide sequence is a fragment of SEQ ID NO:3. Claim 102 states the nucleic acid of claim 97, wherein the regulatory region is selected from the group consisting of a glucocorticoid response motif, a shear stress response motif, an NfκB recognition motif, and an AP1 motif.

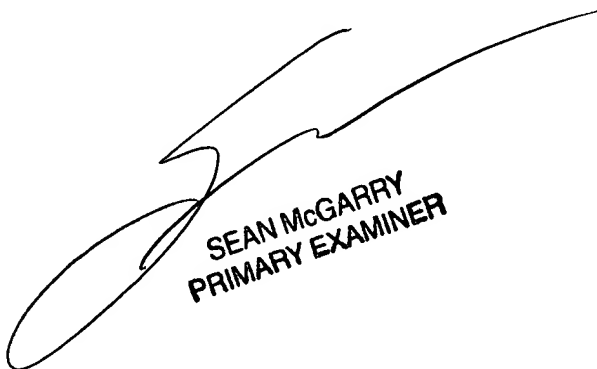
Chojkier et al. taught a use of an oligonucleotide with an NfκB recognition sequence in their SEQ ID NO:1, 5' GGG GAC TTT CCC 3'.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Inquiries relating to the status of this application may also be directed to *Katrina Turner*, whose telephone number is (703) 305-3413.



SEAN MCGARRY
PRIMARY EXAMINER

M. M. Schmidt
February 24, 2003